

EXHIBIT 10

Takeda Pharm. Co. et al. v. Zydus Pharms. (USA) Inc.

Civil Action No. 3:10-CV-01723- JAP-TJB (D.N.J.)

Plaintiffs' Markman Hearing Presentation

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'994/'942 Teach Light Diffraction Measurement of Average Particle Size

“Average particle diameter” means volume based distribution median diameter (median diameter: 50% particle diameter from cumulative distribution), unless otherwise specified. It can be measured by, for example, a laser diffraction particle distribution measurement method. Concretely exemplified is a method using Raser Diffraction Analyzer, type: HEROS RODOS [trade name; manufactured by Sympatec (Germany)].

Ex. 1, '994 patent, Col. 5, ll. 46-47

(5) Average Particle Diameter: Volume Based Distribution Median Diameter (median diameter: 50% Particle Diameter from Cumulative Distribution)

Determination was carried out with Raser Diffraction Analyzer, type; HEROS RODOS [trade name, manufactured by Sympatec (Germany)].

Ex. 1, '994 patent, Col. 19, ll. 32-37

Average Particle Diameter Incorporates a +/- 10% Variation

PQRI Recommendations on Particle-Size Analysis of Drug Substances Used in Oral Dosage Forms

The Product Quality Research Institute (PQRI) is a collaborative process involving the Center for Drug Evaluation and Research (CDER) in Federal Drug Administration (FDA), Industry, and Academia. The mission of PQRI is to conduct research to generate scientific information to support regulatory policy. This initiative aids in identifying the types of product quality information that should be submitted in a regulatory filing to CDER. PQRI has been evolving since

Precision—Repeatability

- Suggested Acceptance Criteria (USP/NF <429>)—Example Laser Diffraction: *Individual or specific applications may require something different.*
 - a. For any chosen central value of the distribution (x_{90}), the %RSD is <10%.
 - b. For values on the edge of distribution (x_{10} or x_{90}), the %RSD is <15%.
 - c. If these values are less than 10 μm , then the %RSD maxima may be doubled.

Ex. 6, Snorek et al., *J. of Pharm. Sci.*, Vol. 96, No. 6, 1451 (June 2007)